Letters

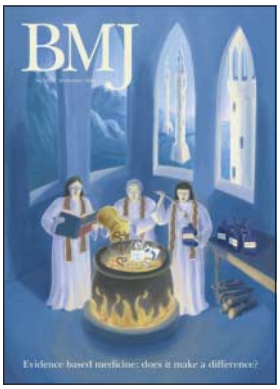
Evidence based medicine: does it make a difference?

Use wisely

EDITOR—The term "evidence based medicine" entered the scientific lexicon only a little more than a decade ago.[1] What caused its remarkable spread, and what are the implications of its broad and rapid diffusion?

The team that coined the term at first considered using the phrase "scientific medicine" but rejected it because it implied that other approaches were by definition unscientific.[2] However, critics have argued that the term evidence based medicine carries a similar moral valence and linguistic slipperiness.[3] Who could argue against the notion of providing care that integrates individual clinical skill and the best external evidence?[4]

Originally developed as a method for teaching medical residents, evidence based medicine is being applied ever more broadly to the organisation and delivery of medical services. Multiple stakeholders now seek to assume its mantle for purposes that often contradict its original intent.



Managers, equating lack of evidence with lack of effectiveness, use it as a rationale for cutting services. Industry generates evidence of questionable quality to promote its products. Medical researchers come to believe that they hold a monopoly on generating and interpreting evidence. Evidence based medicine, developed as a means of taming the unscientific and messy world of clinical practice, has itself entered the unscientific and messy world of politics.[5]

Like any technology, evidence based medicine carries risks and benefits and can be used appropriately or inappropriately. Overly inclusive definitions threaten to deprive the term of meaning, and unchecked use increases the risk of misuse. In the past decade, evidence based medicine has contributed much to how we teach, deliver, and think about clinical services. In the coming decade, we must continue to ensure that it is not only used widely but wisely.

Benjamin Druss *Rosalynn Carter chair in mental health*
Rollins School of Public Health, Emory University, 1518 Clifton Road NE, Atlanta, GA 30322, USA
bdruss@emory.edu

Competing interests: None declared.

1 Guyatt G, Cook D, Haynes B. Evidence based medicine has come a long way. *BMJ* 2004;329; 990-1. (30 October.)
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Make it evidence informed practice with a little wisdom

EDITOR—In the theme issue on whether evidence based medicine makes a difference Gabbay and le May ask whether guidelines are evidence based or "mindlines" that have been constructed collectively.[1] It is clearly time to change "evidence based medicine" to "evidence informed practice."[2] Although "EBMers" have emphasised the importance of patients' values in decision making, this is missed in most discussions.

So that evidence is not displaced by mutant memes on the excuse that evidence ignores values and context (it doesn't), I suggest the era of evidence informed rather than evidence based medicine has arrived. I imagine patients would be either puzzled or concerned by this article and the subsequent discussion.[3]

When I am a patient I would like the (shared) decision making in the consultation to be informed by current best evidence for my condition. That doesn't mean a slavish obedience to results from randomised controlled trials. It means that good evidence forms part of the discussions. I would like to know what good evidence I might be potentially ignoring so that I can reach an informed decision: as either patient or doctor. The "mindlines" described accord with what I see—and may be helpful if they enrich the context of evidence (problems to watch out for or tips for doing the intervention). But the mindlines and memes are worrying if they supply counterfeit evidence: bad money drives out good money. Some recent mindlines and memes include hormone replacement therapy, bed rest for almost anything, and extraction of asymptomatic wisdom teeth.

So a puzzle remains: how do we get valid memes into the mindlines while not driving out the wisdom of experience? I suggest we start with evidence informed medicine and add a little wisdom.

Paul Glasziou *general practitioner*
Centre for Evidence-Based Medicine, University of Oxford, Oxford OX3 7LF
Paul.glasziou@public-health.oxford.ac.uk

Competing interests: PPG is director of the Centre for Evidence-Based Medicine at Oxford (which may have to change its name).

1 Gabbay J, le May A. Evidence based guidelines or collectively constructed "mindlines?" Ethnographic study of knowledge management in primary care. *BMJ* 2004;329:1013-6. (30 October.)
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Management of complex systems needs new approaches

EDITOR—Gabbay and le May's study on how primary care practitioners decide and use knowledge identifies a polarisation in healthcare research and development.[1] On the one side are those who see health care as a linear system that can be understood by reduction to its component parts with a simple relation between cause and effect. On the other side are those who see the system as inherently complex, in which input and output relations are uncertain but patterns emerge that could not be predicted on the basis of analysing the underlying parts.

Although the subject is in its infancy, non-linear systems theory is beginning to offer new approaches to investigating complex systems.[2 3] The trick is to match the analytical approach to the complexity of the system under study. Complex environments need regulatory systems that match their complexity. The current modernisation agenda reflects a reductionist approach that inhibits the development of mindlines and mindfulness which is detrimental to the evolution of systems.

David P Kernick *general practitioner*
St Thomas Health Centre, Exeter EX4 1HJ
Sul838@eclipse.co.uk

Competing interests: None declared.

1 Gabbay J, le May A. Evidence based guidelines or collectively constructed "mindlines?" Ethnographic study of knowledge management in primary care. *BMJ* 2004;329:1013-6. (30 October.)
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In Germany disease is treated via patients' clinical pictures rather than by following mindlines

EDITOR—Gabbay and le May put into focus the processes of "collective sense making" by which knowledge, both explicit and tacit and from whatever sources, is negotiated, constructed, and internalised in routine practice.[1] They identified mindlines replacing guidelines in daily practice. If these processes of collective sense making are assumed to be shaped by, among other factors, culture and training, I wonder whether the social construct of mindlines is also a valid approximation for other countries.

For Germany I think that a similar study would reveal neither mindlines nor other linear structures. Instead of the linear, algorithm driven process commonly used in Anglo-Saxon practice, in Germany the process of diagnosis might better be described as adjusting memorised disease patterns to the clinical pictures of patients. The experience of a doctor is reflected by an increased number of actively retrievable disease patterns. The linguistic equivalent would be the term *Krankheitsbild*, "disease image" rather than "clinical picture," thought of as representing the essential character of a disease rather than the mere symptoms. *Krankheitsbilder* are structuring lecture series for medical students and seem to shape the structure that underlies clinical thinking in Germany.

To overcome the deep rooted resistance against evidence based medicine in Germany, clinical practice would need to win minds and hearts. A first step would be accepting that the predominant processes of collective sense making—namely, adjusting disease patterns with clinical pictures—might not be fully compatible with following linear algorithm oriented guidelines.

Ansgar Gerhardus *research associate*
Department of Epidemiology, Social Medicine, and Health System Research, Hanover Medical School, D-30623 Hanover, Germany
Gerhardus.ansgar@mh-hannover.de

Competing interests: None declared.

1 Gabbay J, le May A. Evidence based guidelines or collectively constructed "mindlines?" Ethnographic study of knowledge management in primary care. *BMJ* 2004;329:1013-6. (30 October.)

Evidence base is weak and comes too late for evidence based policy making

EDITOR—Muir Gray says that evidence based policy making is about taking decisions based on evidence and the needs and values of the population.[1] Surely one of the major barriers to better evidence based policy is that the evidence base is weak and too late.

In clinical practice, evidence in randomised controlled trials often uses selected groups of patients, excluding those with inconvenient comorbidities who would spoil the trial design. Yet these are the very patients who would benefit from the evidence base. Therefore, when a general practitioner tries to explain the risks and benefits of the options for managing atrial fibrillation to a patient with depression, the decision has to be made on some trial, some knowledge of pharmocokinetics, and lots of guesswork.

So it is with policy. How can we tell whether a policy will or will not work in a different time frame, environment, or context if the trials do not exist? All we can be certain of is that the policy will have some effect and be reasonably sure of the sense of direction. Policy making occurs within a social context.[1] That context changes rapidly, in terms of broader social issues but also politically. The evidence base (research) has difficulty keeping up with these changes, so by the time the evaluation, report, or study has been published, things have moved on. This implies the need for formative rather than summative research methods.

The one hope is when the policy comes round again. Practice based commissioning, although different in many important ways from general practitioner fundholding and occurring in a different system, can learn from previous research on primary care led commissioning. Maybe we need to look constantly to rediscover lost policies in the hope they will have a sound evidence base behind them.

Tim Wilson *general practitioner*
Mill Stream Surgery, Benson, Oxfordshire OX10 6RL
Tim.wilson@gp-k84036.nhs.uk

Competing interests: None declared.

1 Muir Gray JA. Evidence based policy making. *BMJ* 2004;329:988-9. (30 October.)

Numerophobia may be a problem in adopting evidence based medicine…

EDITOR—Both the editorial by Del Mar et al and the paper by Straus et al raise important points that must be considered if both medical students and doctors are to be trained successfully in evidence based practice.[1 2]

Del Mar et al say that epidemiology and statistics are repellent to many doctors. In our experience, neither topic is repellent. However, feedback from medical students at the end of our clinical epidemiology course has consistently raised concerns about the ability of students without A level mathematics (a higher school qualification in the United Kingdom) to cope with the biostatistics component of the course, although no complex mathematical calculations are required. We therefore examined this empirically by comparing the exam performance of such students with that of their peers with A level mathematics and did not find any evidence that they were any less competent, at least as assessed by a written exam paper entailing critical appraisal (−1.1% difference in means for students without v those with A level mathematics, 95% CI −3.1% to 0.8%, P = 0.20 based on 498 first year medical students).[3]

We believe that some students experience "numerophobia"—a perceived and disproportionate fear of numbers and simple mathematical manipulation. Interestingly, new cohorts of students have not raised this issue since we started to present these data to them at the beginning of our course.

Other evidence shows that this problem is also common among doctors.[4] Some doctors react antagonistically to evidence based medicine because it ignores the individual patient, takes too long, often lacks evidence, and is too much like "cookbook" medicine. Numerophobia should be added to this list and consideration be given to how to overcome it.

Yoav Ben-Shlomo *senior lecturer in clinical epidemiology*
Department of Social Medicine, University of Bristol, Bristol BS8 2PR
y-ben-shlomo@bristol.ac.uk

Competing interests: None declared.

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…as may be a top down approach

EDITOR—Garner et al reported a framework for shifting the clinical community towards using systematic reviews and evidence based medicine in low and middle income countries.[1] Their proposed structure tries to help implementation of evidence based medicine in a "top down" direction and through targeting groups with specific roles ("health ministry policy makers, professional groups, and managers with responsibility for clinical and public health policy").

They did not consider another major group of users. We think that the resistance of direct care providers (clinicians, nurses, dentists, etc) to changes in clinical routines must be considered. In many parts of the developing world the essential concepts of evidence based medicine have not yet been incorporated by a considerable proportion of clinicians, and opinion based medicine still dominates.

Moreover, although the framework by Garner et al seems powerful for changing the behaviour of clinicians with regard to some common and profound clinical errors, it cannot change the attitude of clinicians towards evidence based medicine and is not practical for numerous minor clinical errors (which clinicians themselves should overcome by using evidence based medicine). With the suggested approach, the rate of exploitation of much available evidence would not be changed, and most systematic reviews and other valuable evidences would be still unused.

We think that, beside the proposed framework (implementation top down), the use of evidence should be promoted by evolution of evidence based culture among all members of the clinical community (dissemination bottom up). The foundation stones for an evidence based medicine "culture" should be laid by undergraduate students and prospective clinicians. Moving towards these goals needs education frameworks for policy makers as well as clinicians.

Alireza Moayyeri *research fellow, evidence based medicine working team*
Akbar Soltani *assistant professor in endocrinology*
soltania@sina.tums.ac.ir
EBM Working Team, Endocrinology and Metabolism Research Center, Shariati Hospital, Tehran University of Medical Sciences, Tehran, Iran

Competing interests: None declared.

1 Garner P, Meremikwu M, Volmink J, Xu Q, Smith H. Putting evidence into practice: how middle and low income countries "get it together." *BMJ* 2004;329:1036-9. (30 October.)

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Summary of webchat

Editor—The webchat on what's the evidence that evidence based medicine (EBM) changes anything raised more questions than answers.[1] Participants started by outlining current challenges: the problems with defining evidence; the impact of teaching EBM; how to use evidence in clinical practice (practising EBM in real time) and integrate it with other sources of information; the role of patients, colleagues, and other eminent figures for those wishing to practise EBM; and the role of continuing medical education in facilitating clinical practice of EBM.

Many problems centre on who decides what evidence is, how it is defined, and its constantly changing nature. If people use different sources of information, do all of them count as evidence?

In the United States "evidence based" seems to be used increasingly in business, for insurance or state sponsored preferred drug lists. And in psychiatry the term has been adopted so fast that even psychiatrists find it difficult to say whether it has become another empty metaphor. Whether EBM would stand up in a court of law, and whether non-evidence based practice would lead to litigation, is also important in defining the term.

Using inadequate evidence may be harmful, and evidence is often unbalanced when EBM is incorporated into professional training. Publications can seek balance in various ways, and the way research is done, indexed, and reported has to be improved. Good and balanced applications need to be distinguished from bad ones.

Patients need to be informed about risks and benefits to be involved in their treatment. But they interpret evidence through their own values and beliefs and often very differently from their doctor. The challenge lies in incorporating these values and still treating patients effectively. Commercial and academic research looks for short term outcomes, so how does this affect patients with long term conditions? If a doctor chooses a non-evidence based treatment, how does it affect EBM publications?

EBM can be practised either as a doer, who practises five steps, or as a replicator, who identifies a practitioner and replicates his or her practice. Eminent role models thus play a part, as do students, who can help change practice from the bottom upwards, like "infectious vectors" of new ideas. Teachers need to be open to these new ideas.

One of the barriers to practising EBM may be that doctors gather information non-critically from convenient sources. This could be counteracted by getting more good evidence into the pool and teaching people to select appropriately, or by copying experts with a track record of systematically seeking, appraising, and using evidence. Doctors may be too tired to practise EBM, or they may even be envious of well informed patients. The General Medical Council's revalidation procedures should stop "myths" that aren't evidence from being passed around among doctors. Peer pressure might also help. Providers of continuing medical education need to make their sessions more evidence based.

EBM is not about the latest evidence but about integrating all the available evidence, including qualitative research, and ensuring that the most recent article is evaluated in the context of existing knowledge. "Evidence informed practice" or "evidence informed medicine" might ensure that doctors did not mistakenly think that they could act only on perfect evidence (which does not exist).

Birte Twisselmann *technical editor*
BMJ

Competing interests: None declared.

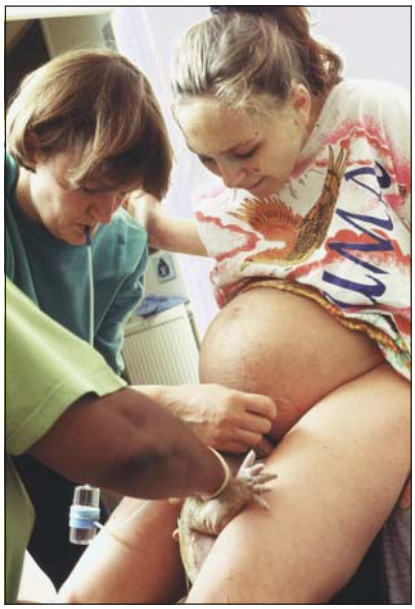
1 Webchat transcript. Thursday 4 November 2004. What's the evidence that evidence based medicine changes anything? http://bmj.bmjjournals.com/cgi/content/full/329/7474/DC1 (accessed 21 Dec 2004).

Inappropriateness of randomised trials for complex phenomena

Single trial is never enough evidence to base decisions on

Editor—Kotaska outlines the importance of care providers' skill and the experience of a unit when assessing non-pharmacological treatments such as vaginal breech delivery in randomised trials.[1] We agree that evaluation of non-pharmacological treatment raises specific methodological issues, including the skill of care providers.[2]

Care providers are part of the intervention to be tested, and having highly skilled or experienced care providers in one arm and low skilled or less experienced care providers in the other could lead to bias. Equally, bias can occur when care providers have more experience in performing one of the interventions tested than the other. However, appropriate methodological planning of randomised trials could circumvent this bias. To allow the surgical procedure to be assessed in the context of the skills required to achieve it, care providers participating in a surgery trial could be trained and selected only if they achieve set standards,[3] selected according to their experience of the procedure,[4] or patients could be randomised not to operations but to care providers, who would deliver their treatment of preference.[5]



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Vaginal breech delivery is a complex procedure

Kotaska's article was an interesting example of potential bias linked to care providers' experience; the author generalises when concluding that complex procedures are poorly amenable to the methods of large multicentre randomised trials. Condemning all multicentre randomised trials that assess complex interventions when considering one imperfect randomised controlled trial seems as inappropriate as defining a new standard of care for vaginal breech delivery based on a single trial that is potentially biased.

Isabelle Boutron *research fellow*
Isabelle.boultron@bch.ap-hop-paris.fr
Philippe Ravaud *head*
Département d'Epidémiologie, Biostatistique et Recherche Clinique, INSERM EMI 0357, Groupe Hospitalier Bichat-Claude Bernard (AP-HP), Faculté de Médecine Xavier Bichat, Université Paris VII, 46 rue Henri Huchard, 75877 Paris, France
Bruno Giraudeau *assistant professor*
INSERM CIC 202, Tours, France

Competing interests: None declared.

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Are the results of the term breech trial generalisable?

EDITOR—In the term breech trial planned caesarean section was associated with a lower risk of death and initial serious morbidity, for singleton breech babies at term, compared with planned vaginal birth, although no benefit of planned caesarean was evident at 2 years of age.[1 2]

Kotaska does not believe that these results are generalisable and thinks that practitioners must have pushed their comfort level for vaginal breech delivery to achieve a vaginal delivery rate of 57%.[3] However, this rate was for women having a trial of labour and is similar to rates found in published reports.[3]

Kotaska also criticises the selection criteria and the intrapartum management of women planning a vaginal breech delivery in the trial, despite the fact that the protocol was developed at a consensus workshop by a group of obstetricians who were recognised in their communities as expert at vaginal breech delivery, and was then vetted by experienced obstetricians worldwide.[4]

We agree that operators' skill is crucially important in evaluating surgical interventions but continue to believe that randomised controlled trials provide the best evidence as to whether such procedures cause more good than harm.[5] We sympathise with practitioners who do not believe that the results of the term breech trial apply to them. No one was more disappointed with the findings of the trial than the participating clinicians themselves who believed in the safety of vaginal breech delivery but were willing to put their vaginal breech delivery skills to the test.

Mary Hannah *director*
University of Toronto Maternal Infant and Reproductive Health Research Unit, Centre for Research in Women's Health, Suite 751,790 Bay Street, Toronto, ON, Canada M6G 1N8
Mary.Hannah@sw.ca

Competing interests: None declared.

For the Term Breech Trial Steering Committee and Collaborative Group

1 Hannah ME, Hannah WJ, Hewson S, Hodnett E, Saigal S, Willan A, for the Term Breech Trial Collaborative Group. Planned caesarean section versus planned vaginal birth for breech presentation at term: a randomised multicentre trial. *Lancet* 2000;356:1375-83.
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Author's reply

EDITOR—Boutron et al misquote a summary point to suggest that all complex procedures are not amenable to randomised investigation. They note that randomisation within a system of procedural excellence (not in 121 centres in 26 countries) can be a useful investigational tool. This certainly is the case; however, one must remember that procedural excellence always remains in evolution.

Wide variations in confidence and success rates illustrate the dynamic and evolving nature of vaginal breech delivery.[1 2] All major advances in technique have occurred in Europe—notable were Bracht's and Thiessen's introduction of a one-phase spontaneous birth resulting in the largest published decrease in perinatal breech mortality.[3 4] Experienced European centres showing safety in vaginal breech delivery with these techniques were underrepresented in the term breech trial, partly because some declined to participate.

In contrast, the term breech trial was based in North America, where the vaginal breech birth rate is a quarter that in Norway or the Netherlands. The protocol superficially outlined a two-phase birth, neglecting techniques that are widespread in Europe and largely responsible for safe success with vaginal breech birth.[5] Despite its design by North American experts, and its international vetting (minimally in Norway, Ireland, France, the Netherlands, Austria, and Germany), the protocol represented a simplified and outdated approach, comparatively less safe for achieving a vaginal breech birth rate >50%. Declaring this standard the best achievable because it was studied in a randomised fashion seriously breaches the limits of evidence based medicine.

Hannah's suggestion that centres with expertise mount their own randomised trial does not acknowledge that these centres have already shown safety through self audit. As Boutron notes, complex procedures must be analysed adequately and mastered before they can be randomised. In its enthusiasm for the methodological gold standard, the term breech trial put the cart before the horse.

Andrew Kotaska *resident*
Department of Obstetrics and Gynaecology, University of British Columbia, Women's Hospital, Vancouver, BC, Canada V6H 3V5
Kotaska@bulkley.net

Competing interests: None declared.

1 Diro M, Puangsricharen A, Royer L, O'Sullivan MJ, Burkett G. Singleton term breech deliveries in nulliparous and multiparous women: a 5-year experience at the University of Miami/Jackson Memorial Hospital. *Am J Obstet Gynecol* 1999;181:247-52.
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Rationale for psychostimulants in ADHD

EDITOR—Confusion about levels of diagnosis causes most debate about psychostimulants in childhood behavioural disorders.[1] DSM-IV definitions are all syndromes—that is, symptoms and signs unrelated to pathology and aetiology. Most effective therapies treat pathology and aetiology; syndromes can be treated only symptomatically. The syndrome of chronic diarrhoea is analogous. Gluten intolerance is one cause. If we suspect this clinically, we test the person by gluten challenge. Clinical improvement on withdrawal and relapse on challenge confirms the diagnosis. No clinical response excludes gluten intolerance. Most chronic diarrhoeas have other causes, and some persons with proved gluten intolerance have other clinical features.

Research has found defects in dopamine transport in the brains of children with clinical attention deficit hyperactivity disorder.[2 3] Some children with the biochemical defect have other symptoms; some are clinically normal. Some with clinical attention deficit hyperactivity disorder are biochemically normal. Clinical and biochemical changes overlap but do not coincide. We can call the clinical condition "attention deficit hyperactivity syndrome" and the biochemical disorder "stimulant responsive behavioural disorder." Symptoms in children with the biochemical disorder improve dramatically with psychostimulants.[4] A formal, short term trial is needed. We should give long term psychostimulants only when the symptoms are severe but not necessarily typical of attention deficit hyperactivity syndrome, improve on psychostimulants, and return when they are stopped.

Stimulant responsive behavioural disorder is a group of defects of dopamine transport in the brain, with varying clinical expressions, including the attention deficit hyperactivity syndrome, but that syndrome also has other causes. Separating the biochemical disorder and clinical syndrome promotes the rational use of psychostimulant drugs.

Alan Dugdale *consultant paediatrician*
Department of Paediatrics and Child Health, University of Queensland, St Lucia, QLD 4067, Australia
A.Dugdale@uq.edu.au

Competing interests: None declared.

1 Marcovitch H. Use of stimulants for attention deficit hyperactivity disorder: AGAINST. *BMJ* 2004;329:908-9. (16 October.)
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Impact of congenital colour vision deficiency

Congenital colour vision deficiency does cause problems

Editor—Cumberland et al did not find a significant association between colour vision deficiency and either educational attainment or the occurrence of personal injury.[1] They conclude that normal colour vision is not a prerequisite for safe driving or working, saying that their findings challenge the rationale of population screening for colour vision deficiency.

The conclusions are quite a leap and not at all helpful for people with this condition. Almost all report some problems with colour: 30% in recognising road traffic signal lights and 13% in seeing brake lights of cars. Over 33% say their colour deficiency affected their choice of career, and 25% report that they have problems with colour in their present job; 75% have everyday problems when making judgments about colour.[2]

Some occupations preclude people with colour deficiency because colour recognition is crucial, and such deficiency is a serious handicap for many occupations, including medicine and the graphic and creative arts.[3 4] The educational attainment of people with colour vision deficiency may not be affected in the long term, but they are embarrassed and anxious when their teacher identifies objects by colour or they are asked to use specific colours.[3]

Colour vision deficiency is a risk factor for driving.[3] The studies that failed to show that it is a risk factor had samples too small to identify the expected level of risk.[5] Schoolchildren should know if they have colour vision deficiency so they can be helped more quickly to find adaptive strategies and be able to take it into account when planning their career.

Barry L Cole *professor emeritus*
University of Melbourne, Victoria 3010, Australia
bcole@optometry.unimelb.edu.au

Competing interests: None declared.

1 Cumberland P, Rahi JS, Peckham CS. Impact of congenital colour vision deficiency on education and unintentional injuries: findings from the 1958 British birth cohort. *BMJ* 2004;329:1074-5. (6 November.)
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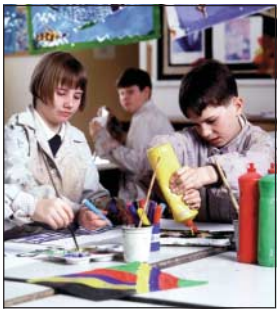
Screening could help choice of medical career

Editor—Cumberland et al studied the impact of colour vision deficiency on education and unintentional injuries.[1] I have this condition (albeit the less impairing red-green variant) and offer my experience of studying medicine.

I had great difficulty in discerning where, during surgical procedures, muscle fibres ended and tendon fibres started—I could not see the difference in colour. The same thing applied to other structures, which, as you can imagine, made me less than suited for a career in surgery.

Later, during my internship in paediatrics, I noticed that I could never see what others would call "masking" (the slight bluish tinge around the mouth of a very ill infant) or the yellowish colour of impending bilirubinaemia. All in all, I lacked the "clinical eye" that is crucial in paediatrics.


STEVE LYNE/REX

Therefore I strongly recommend introducing a test for colour vision deficiency at the start of medical education to preclude unnecessary disappointment and help choose a medical career.

Pieter A Wiegersma *lecturer*
University of Groningen, A Deusinglaan 1, 9713 AV Groningen, Netherlands
p.a.wiegersma@med.rug.nl

Competing interests: None declared.

1 Cumberland P, Rahi JS, Peckham CS. Impact of congenital colour vision deficiency on education and unintentional injuries: findings from the 1958 British birth cohort. *BMJ* 2004;329:1074-5. (6 November.)

Poor colour vision does not have to be a hindrance

Editor— The data of Cumberland et al suggest that screening for colour blindness may not be necessary.[1] My colour "blindness" was not discovered until I was 19 during a medical examination for airforce pilots. Needless to say that was the end of any possible airforce career.

At the time I was working in an advertising agency, and it was part of my job to correct colour photographic proofs. I knew that my colour vision was not particularly good but put it down to having missed colour lessons at school. On reflection, I now realise that I automatically tended to refer to shape, form, shading, position—in fact, anything rather than a picture's colour. Being smacked on the head by a primary school art teacher for having been stupid in drawing purple sky and brown grass may have contributed to this.

Now, as a physiotherapist, I do not have any difficulty with assessing patients. Bruising, blanching, ecchymosis, and other colour changes are just as visible to me as to my "normal" colleagues. Maybe I cannot distinguish the colour accurately, but acuity is undiminished. From a practical perspective, having defective colour vision has made no difference to my life, apart from realising I need help in choosing colours for combinations of clothes.

Robert G M Sellars *physiotherapist*
FCE Systems, PO Box 9469, Newmarket, New Zealand 1031
bob.sellars@paradise.net.nz

Competing interests: None declared.

1 Cumberland P, Rahi JS, Peckham CS. Impact of congenital colour vision deficiency on education and unintentional injuries: findings from the 1958 British birth cohort. *BMJ* 2004;329:1074-5. (6 November.)

Authors' reply

Editor—We recognise that people with colour vision defects can experience difficulties in everyday life. These vary according to the nature and severity of the condition as well as the personal circumstances of the affected person and the ability to develop adaptive strategies, as illustrated by Wiegersma and Sellars and on bmj.com.[1]

Several criteria have to be met to justify whole population screening,[2] in particular that colour vision defects have an important impact on major life course outcomes at the population level (on "average"), which can be avoided by early detection. Thus we reported highest educational attainment and risk of serious accidents requiring hospital care and investigated these outcomes in a sufficiently large and representative population.

The current rationale for school screening for colour vision defects in the United Kingdom is potential preclusion from occupations, although international differences in statutory requirements for colour vision identify inconsistencies in the evidence base. Nevertheless, balancing the rights of an individual to pursue his or her chosen career with the social and economic costs of "mistakes" attributable to colour vision defects is currently being debated.[3]

An editorial decision meant that our data on employment history and occupational choice presented in our original manuscript were not included in our paper. A separate report of these findings is currently under review. Existing data are limited but indicate that screening at 11 years is not necessarily the most effective way to identify and inform those with colour vision defects.[4]

Young people need to know their precise colour vision status before making occupational choices. This requires assessment for particular contexts: this is not the purpose of school screening as currently practised in the United Kingdom.

Jugnoo S Rahi *clinical senior lecturer in ophthalmic epidemiology*
j.rahi@ich.ucl.ac.uk
Phillippa Cumberland *senior research fellow*
Catherine S Peckham *professor of paediatric epidemiology*
Centre for Paediatric Epidemiology and Biostatistics, Institute of Child Health, London WC1N 1EH

Competing interests: None declared.

1 Electronic responses. Impact of congenital colour vision deficiency on education and unintentional injuries. bmj.com 2004. http://bmj.bmjjournals.com/cgi/eletters/329/7474/1074 (accessed 22 Dec 2004).
2 UK National Screening Committee. Criteria for appraising the viability, effectiveness and appropriateness of a screening programme. www.nsc.nhs.uk/uk_nsc/uk_nsc_ind.htm (accessed 22 Dec 2004).
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4 Holroyd E, Hall DMB. A re-appraisal of screening for colour vision impairments. *Child Care Health Dev* 1997; 23:391-8.